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	stitute for form 1449A/	в/РТО	_	Complete if Known		
•			·	Application Number	10/791,148	
11	IFORMATI	ON DIS	CLOSURE	Filing Date	March 1, 2004	
S	TATEMEN'	T BY A	PPLICANT	First Named Inventor	Amedeo Leonardi	
•				Art Unit	1614	
	(Use as man	y sheets as	necessary)	Examiner Name	TBA	
Sheet	1	of	3	Attorney Docket Number	04266/100M619-US3	

	U.S. PATENT DOCUMENTS						
Examiner Initials*	Cita	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where		
	Cite No.1	Number-Kind Code ² (if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear		
505	Α	6,517,871	02/11/2003	Venkatesh et al.			
	В	6,395,728	05/28/2002	Webb et al.	·		
	C	6,204,281	03/20/2001	Webb et al.			
	D	6,071,939	06/06/2000	Gaviraghi et al.			
	E	2004/0254176	12/16/2004	Grigorieff et al.			
\$	F	2004/0002529	01/01/2004	Sada et al.			
:	G	2003/0181500	09/25/2003	Lee et al.			
•	Н	2003/0175344	09/18/2003	Wald et al.			
	1	2003/0008904	01/09/2003	Buch, Jan			
	J	2002/0098241	07/25/2002	Venkatesh, Gopadi M.			

:		FOREI	GN PATENT	DOCUMENTS		
Examiner Initials*	Cite No. 1 Country Code ³ -Number 4-Kind Code ⁵ (if known) MM-DD-YYYY		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
503	1	WO 03/097045	11/27/2003	Novartis Pharma GMBH	-	_
1	2	WO 03/014084	02/20/2003	Recordati Ireland Limited		
	3	WO 02/43807.	06/06/2002	Novartis AG		П
	4	WO 02/35046	05/02/2002	EGHOLM, et al.		Г
	5	WO 02/06253	01/24/2002	Norvartis-Erfindungen Verwaltungsgesellschaft MBH		
	6	WO 01/13900	03/01/2001	Medicure Inc.		Г
,	7	WO 00/27397	05/18/2000	Glaxo Group Limited, et al.		Г
	8	WO 00/27396	05/18/2000	Glaxo Group Limited, et al.		
	9	WO 00/02543	01/20/2000	Norvartis-Erfindungen Verwaltungsgesellschaft MBH		

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:		NON PATENT LITERATUR	E DOCUMENTS	
Examiner Initials	Cite No.1	include name of the author (in CAPITAL LETTERS), title magazine, journal, serial, symposium, catalog, etc.), d and/or country w	ate, page(s), volume-issue number(s), publisher, city	T²
845	10	Aranda, F.J. et al. (2000) "Therapeutic Efficacy Candesartan, Alone or in Combination, in Mild-Nypertension 18(2): S152 (abstract)	and Tolerability of Lercanidipine versus Moderate Essential Hypertensives," Journal of	
	11	Epstein, MD, Murray (2001) "Lercanidipine - A N Blocker," Heart Disease 3: 398-407	Novel Dihydropyridine Calcium-Channel	
Examiner Signature	1	a Jer	Date Considered 7/18/65	•

PTO/SB/08a/b (08-03)

Approved for use through 07/31/2008. OMB 0851-0031

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Substitut	e for form 1449A	/B/PTO		Complete if Known		
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INF	ORMATI	ON DISC	LOSURE			
STA	TEMEN	T BY AP	PLICANT			
1				Art Unit	1614	
:	(Use as man	y sheets as nec	essary)	Examiner Name	TBA	
Sheet	2	of	3	Attorney Docket Number	04266/100M619-US3	

545	12	Gasser et al. (1999) "Lercanidipine, a new third generation Ca-antagonist in the treatment of hypertension", <i>J Clin Basic Cardiol</i> , 2:169-174
	13	Grandi et al. (2002) "Aldosterone Antagonist Improves Diastolic Function in Essential Hypertension", Hypertension, 40:647-652
	14	Kurashivili, Ramaz B. et al. "24-Hour Monitoring in Hypertensive Patients with Type II Diabetes Mellitus: Combination Therapy with Lacidipine and Irbesartan (undated abstract)
	15	Mancia et al. (1998) "Clinical Advantages of Lipophilic Dihydropyridines", <i>Blood Pressure</i> , 7(suppl 2):23-26
	16	Mancia and Grassi (1994) "Combination treatment of hypertension", High Blood Pressure, 3 (suppl to No. 4): 5-7
	17	Martell et al. (2003) "Association of Lercanidipine Plus Enalapril to Control Blood Pressure," presented at the American Society of Hypertension, May 14-17, 2003, New York, NY (abstract)
10 10 10 10 10 10 10 10 10 10 10 10 10 1	18	Martell et al. (2002) "Asociaciones Terapeúticas en El Control de la Presión Arterial," Poster and Abstract presented at the 7 th Reunión Nacional Sociedad Española de Hipertensión Liga Española para la Lucha contra la Hipertensión Arterial, <i>Hypertensión</i> 19(2), Abstract 61T
	19	Martell et al. (2002) "Asociaciones Farmacologicas en Hipertensos con Fectores de Riesgo Cardiovascular," Poster and Abstract presented at the 7 th Reunión Nacional Sociedad Española de Hipertensión Liga Española para la Lucha contra la Hipertensión Arterial, Hypertensión 19(2), Abstract 69T
	20	McClellan and Jarvis (2000) "Lercanidipine: A Review of its Use in Hypertension", Drugs, 60:1123-1140
	21	Messerli, MD, Franz (2002) "Vasodilatory Edema: A Common Side Effect of Antihypertensive Therapy," Current Cardiology Reports 4: 479-482
	22	Morgan, Trefor et al. (2002) "A Comparison of Candesartan, Felodipine, and Their Combination in the Treatment of Elderly Patients with Systolic Hypertension," American Journal of Hypertension 15(6): 544-549
	23	Omboni and Zanchetti (1998) "Antihypertensive efficacy of lercanidipine at 2.5, 5 and 10mg in mild to moderate essential hypertensives assessed by clinic and ambulatory blood pressure measurements", <i>J Hypertens</i> , 16:1831-1838
	24	Ramsay et al. (1999) "Guidelines for management of hypertension: report of the third working party of the British Hypertension Society", <i>J of Human Hypertension</i> , 13:569-592
	25	Recordati et al. (2000) "Effects of a reversible 'nephrectomy' on renal sympathetic activity and blood pressure in the rat: evidence for an acute angiotensin-mediated hypertension", <i>Journal of Hypertension</i> , 18:1277-1287
	26	Rengo and Romis (1997) "Activity of Lercanidipine in Double-Blind Comparison with Nitrendipine in Combination Treatment of Patients with Resistant Essential Hypertension", J of Cardiovascular Pharmacology, 29(suppl 2):S54-S58
	27	Ruzicka, MD, Marcel et al. (2002) "Combination therapy as first-line treatment of arterial hypertension," Can. J. Cardiol. 18(12): 1317-1327
:	28	Sarafidis et al. (2004) "The Effect of Telmisartan and Lekamidipine on Blood Pressure and Insulin Resistance in Hypertensive Patients," Review of Clinical Pharmacology and Pharmacokinetics, International Edition 18:60-66

Examiner Signature	Date Considered 7(19/65	٦
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She	et	3	of	3	Attorney Docket Number	04266/100M619-US3	

SUS	29	van Zwieten (2000) "The influence of antihypertensive drug treatment on the prevention and regression of left ventricular hypertrophy", Cardiovascular Research, 45:82-91	
	30	Weir AJH (1998) *The Rationale for Combination Versus Single-Entity Therapy in Hypertension*, American Journal of Hypertension, 11:163S-169S	

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